

STATEMENT OF EMERGENCY

907 KAR 1:028E

(1) This emergency administrative regulation is promulgated to revise laboratory director requirements in response to an order from the Honorable Justice Phillip Shepherd of the Franklin Circuit Court regarding Aegis Science Corporation v. CHFS, Franklin Circuit Court No. 07-CI-01024 and to comply with KRS 333.090.

(2) This action must be taken on an emergency basis, in accordance with KRS 13A.190(1)(a)3., to comply with an order from the Honorable Justice Phillip Shepherd of the Franklin Circuit Court regarding Aegis Science Corporation v. CHFS, Franklin Circuit Court No. 07-CI-01024 and to comply with KRS 333.090.

(3) This emergency administrative regulation shall be replaced by an ordinary administrative regulation filed with the Regulations Compiler.

(4) The ordinary administrative regulation is identical to this emergency administrative regulation.

Steven L. Beshear
Governor

Janie Miller, Secretary
Cabinet for Health and Family Services

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Provider Operations

4 (Emergency Amendment)

5 907 KAR 1:028E. Independent laboratory and radiological service coverage and
6 reimbursement.~~[Other laboratory and x-ray services.]~~

7 RELATES TO: KRS 205.520, 333.090, 42 CFR 440.30, 493, 42 USC 1395l(h)(1)(A),
8 1396a(a)(9), 1396b(i)(7), 1396d

9 STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.560, 42
10 CFR 441.17,~~[EO 2004-726]~~

11 NECESSITY, FUNCTION, AND CONFORMITY: ~~[EO 2004-726, effective July 9, 2004,~~
12 ~~reorganized the Cabinet for Health Services and placed the Department for Medicaid~~
13 ~~Services and the Medicaid Program under the Cabinet for Health and Family Services.]~~

14 The Cabinet for Health and Family Services, Department for Medicaid Services, has
15 responsibility to administer the Medicaid Program. KRS 205.520 authorizes the cabinet,
16 by administrative regulation, to comply with a requirement that may be imposed or
17 opportunity presented by federal law for the provision of medical assistance to Kentucky's
18 indigent citizenry. This administrative regulation establishes the provisions relating to the
19 coverage of and reimbursement for independent laboratory and radiological services.

20 Section 1. Definitions. (1) "CMS" means the Centers for Medicare and Medicaid

1 Services.

2 (2) "CLIA" means the Clinical Laboratory Improvement Amendments.

3 (3) "Covered benefit" or "covered service" means an independent laboratory or
4 radiological service for which the department shall reimburse.

5 (4) "CPT" means the current procedural terminology coding system.

6 (5) "Department" means the Department for Medicaid Services or its designee.

7 (6) "Incidental" means a medical procedure or service which:

8 (a) 1. Is performed at the same time as a more complex primary procedure or service;

9 and

10 2. Requires little additional resources; or

11 (b) Is clinically integral to the performance of the primary procedure or service.

12 (7) "Independent laboratory" means a laboratory which:

13 (a) Is certified by CMS under the CLIA to perform laboratory services;

14 (b) Is independent of an institutional setting;

15 (c) Is a Medicare-participating facility;

16 (d) Meets the requirements established in 42 CFR 493 regarding laboratory
17 certification, registration, or other accreditation as appropriate; and

18 (e) Is a Medicaid-enrolled provider.

19 (8) "Laboratory director" means an individual meeting the director of laboratory
20 qualifications established in KRS 333.090(1), (2), or (3).

21 (9) "Medicaid-enrolled provider" means a provider participating in the Kentucky
22 Medicaid program in accordance with 907 KAR 1:671 and 907 KAR 1:672.

23 (10) "Medically necessary" or "medical necessity" means a covered benefit determined

1 to be needed in accordance with 907 KAR 3:130.

2 (11) "Medicare-participating" means certified by CMS and accepting reimbursement
3 from Medicare.

4 (12) "Mutually exclusive" means two (2) laboratory or radiological services:

5 (a) Not reasonably provided in conjunction with one (1) another during the same
6 patient encounter on the same date of service; or

7 (b) Representing:

8 1. Duplicate or very similar items; or

9 2. Medically inappropriate use of CPT codes.

10 (13) "Prescriber" means a physician, podiatrist, optometrist, dentist, oral surgeon,
11 advanced registered nurse practitioner or physician's assistant who:

12 (a) Is acting within the legal scope of clinical practice under the licensing laws of the
13 state in which the health care provider's medical practice is located;

14 (b) Is in good standing with:

15 1. The licensure board of jurisdiction for the provider's practice; and

16 2. CMS;

17 (c) Has the legal authority to write an order for a medically necessary service for the
18 recipient; and

19 (d) If enrolled as a Kentucky Medicaid provider, is in compliance with all requirements
20 of 907 KAR 1:671 and 907 KAR 1:672.

21 (14) "Radiological service" means a service in which X-rays or rays from radioactive
22 substances are used for diagnostic or therapeutic purposes.

23 (15) "Recipient" is defined in KRS 205.8451(9).

1 (16) “Usual and customary” means the uniform amount which a provider charges the
2 general public for a specific procedure or service.

3 Section 2. Coverage. (1) The department shall reimburse for a procedure provided by
4 an independent laboratory if the procedure:

5 (a) Is one that the laboratory is certified to provide by Medicare and in accordance with
6 907 KAR 1:575;

7 (b) Is a covered service within the CPT code range of 80047 – 89356 except as
8 excluded in Section 3 of this administrative regulation;

9 (c) Is prescribed in writing or by electronic request by a physician, podiatrist, dentist,
10 oral surgeon, advanced registered nurse practitioner, or optometrist; and

11 (d) Is supervised by a laboratory director.

12 (2) The department shall reimburse for a radiological service if the service:

13 (a) Is provided by a facility that:

14 1. Is licensed to provide radiological services;

15 2. Meets the requirements established in 42 CFR 440.30;

16 3. Is certified by Medicare to provide the given service;

17 4. Is a Medicare-participating facility;

18 5. Meets the requirements established in 42 CFR 493 regarding laboratory certification,
19 registration, or other accreditation as appropriate; and

20 6. Is a Medicaid-enrolled provider;

21 (b) Is prescribed in writing or by electronic request by a physician, oral surgeon, dentist,
22 podiatrist, optometrist, advanced registered nurse practitioner, or a physician’s assistant;

23 (c) Is provided under the direction or supervision of a licensed physician; and

1 (d) Is a covered service within the CPT code range of 70010 – 78999.

2 Section 3. Exclusions. The department shall not reimburse for an independent
3 laboratory or radiological service via this administrative regulation for the following
4 services or procedures:

5 (1) A procedure or service with a CPT code of 88300 through 88399;

6 (2) A procedure or service with a CPT code of 89250 through 89356;

7 (3) A service provided to a resident of a nursing facility or an intermediate care facility
8 for individuals with mental retardation or a developmental disability; or

9 (4) A court-ordered laboratory or toxicology test.

10 Section 4. Reimbursement. (1) The department shall reimburse an independent
11 laboratory the current Medicare rate established by CMS:

12 (a) For Kentucky;

13 (b) For the covered service or procedure; and

14 (c) In accordance with 42 USC 1395l(h)(1)(A).

15 (2) Reimbursement for a service provided by an independent laboratory shall not
16 exceed the limit established in 42 USC 1396b(i)(7).

17 (3) The department shall reimburse a Medicaid-enrolled provider licensed to provide
18 radiological services:

19 (a) The provider's usual and customary charge for the service; and

20 (b) Not to exceed sixty (60) percent of the upper payment limit established for the
21 procedure in the Medicaid physician fee schedule pursuant to 907 KAR 3:010.

22 Section 5. Provider Participation Conditions. (1) To be reimbursed by the department
23 for a service provided in accordance with this administrative regulation, a provider of

independent laboratory services or radiological services shall:

(a) Be a Medicaid-enrolled provider;

(b) Comply with 907 KAR 1:005 and 907 KAR 1:673;

(c) Comply with the requirements regarding the confidentiality of personal records pursuant to 42 U.S.C. 1320d-8 and 45 C.F.R. parts 160 and 164; and

(d) Annually submit documentation of:

1. Current CLIA certification to the department if the provider is an independent laboratory; and

2. A current radiological license to the department if the provider provides radiological services.

(2) A provider may bill a recipient for a service not covered by the department if the provider informed the recipient of noncoverage prior to providing the service.

Section 6. Appeal Rights. (1) An appeal of a department decision regarding a recipient based upon an application of this administrative regulation shall be in accordance with 907 KAR 1:563.

(2) An appeal of a department decision regarding Medicaid eligibility of an individual shall be in accordance with 907 KAR 1:560.

(3) An appeal of a department decision regarding a Medicaid provider based upon an application of this administrative regulation shall be in accordance with 907 KAR 1:671.

~~[other laboratory and x-ray services for which payment shall be made by the Medicaid Program in behalf of both the categorically needy and medically needy.~~

~~Section 1. Covered Services.~~

~~(1) A laboratory service provided by a participating independent laboratory shall be~~

1 ~~limited to those procedures:~~

2 ~~(a) For which the laboratory is certified under Medicare and in accordance with 907~~
3 ~~KAR 1:575; and~~

4 ~~(b) Prescribed by a physician, podiatrist, dentist, optometrist, or a person authorized by~~
5 ~~the physician, podiatrist, dentist, or optometrist, if the physician, podiatrist, dentist, or~~
6 ~~optometrist approved the service.~~

7 ~~(2) X-ray services (radiological services including x-rays, ultrasound, computer assisted~~
8 ~~tomography and magnetic resonance imaging) shall be limited to those procedures~~
9 ~~provided by a facility licensed to provide radiological services and which meets the~~
10 ~~requirements of 42 CFR 440.30 with the following limitations:~~

11 ~~(a) The facility shall participate in the Medicare Program;~~

12 ~~(b) The procedure shall be ordered by a licensed physician, oral surgeon, dentist,~~
13 ~~podiatrist, optometrist or a person authorized by the physician, oral surgeon, dentist,~~
14 ~~podiatrist, or optometrist, if the physician, oral surgeon, dentist, podiatrist, or optometrist~~
15 ~~approved of the service;~~

16 ~~(c) The service shall be provided under the direction or supervision of a licensed~~
17 ~~physician; and~~

18 ~~(d) The facility shall meet the requirements of 42 CFR Part 493 with regard to~~
19 ~~laboratory certification, registration or other accreditation as appropriate.~~

20 ~~Section 2. Incorporation by Reference.~~

21 ~~(1) "Independent Laboratory and Other Lab and X-ray Services Manual", August 1996~~
22 ~~edition, Department for Medicaid Services, is incorporated by reference.~~

23 ~~(2) It may be inspected, copied, or obtained at the Department for Medicaid Services,~~

1 ~~Cabinet for Health and Family Services, 275 East Main Street, Frankfort, Kentucky~~
2 ~~40621, Monday through Friday, 8 a.m. to 4:30 p.m.]~~ (Recodified from 904 KAR 1:028, 5-
3 2-86; Am. 12 Ky.R. 1955; eff. 7-2-86; 13 Ky.R. 1795; eff. 5-14-87; 15 Ky.R. 676; eff. 9-21-
4 88; 19 Ky.R. 2147; eff. 4-21-93; 23 Ky.R. 3650; 4199; 24 Ky.R. 118; eff. 6-18-97.)

907 KAR 1:028E

REVIEWED:

Date

Elizabeth A. Johnson, Commissioner
Department for Medicaid Services

APPROVED:

Date

Janie Miller, Secretary
Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 1:028E

Cabinet for Health and Family Services

Department for Medicaid Services

Agency Contact Person: Patricia Biggs or Charles Douglass at (502) 564-2687; Stuart Owen at (502) 564-4321

- (1) Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation establishes Department for Medicaid Services (DMS) provisions relating to independent laboratory and radiological service coverage and reimbursement.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to establish DMS provisions relating to independent laboratory and radiological service coverage and reimbursement.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing DMS provisions relating to independent laboratory and radiological service coverage and reimbursement.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing DMS' coverage of and reimbursement for independent laboratory and radiological services.
- (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: The primary amendment conforms to the laboratory director requirements (definition) with Kentucky law (KRS 333.090) and in response to a Franklin Circuit Court order (Aegis Science Corporation v. CHFS, Franklin Circuit Court No. 17-CI-01024). Previously DMS required, in a manual incorporated by reference, laboratory staff to be supervised by a board-certified pathologist; however, the laboratory director qualifications established in KRS 333.090 are broader in scope. Additional amendments include adding laboratory reimbursement provisions, previously established in 907 KAR 1:029, into this administrative regulation; un-incorporating the Independent Laboratory and Other Lab and X-ray Services Manual from reference as policies are being inserted into the administrative regulation itself; clarifying policies; and formatting and language revisions to comply with KRS 13A.
 - (b) The necessity of the amendment to this administrative regulation: The amendment is necessary to comply with KRS 333.090 and with a Franklin Circuit Court order.
 - (c) How the amendment conforms to the content of the authorizing statutes: The amendment conforms to the content of the authorizing statutes by adopting the statutory (KRS 333.090) laboratory director requirements and complies with a

Franklin Circuit Court order.

- (d) How the amendment will assist in the effective administration of the statutes
The amendment will assist in the effective administration of the authorizing statutes by adopting the statutory (KRS 333.090) laboratory director requirements and complies with a Franklin Circuit Court order.
- (3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: Any provider restricted from provided services previously due to the prior laboratory staff supervision requirement could potentially qualify as a provider as a result of the amendment.
- (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The amendment broadens laboratory director requirements to those established in KRS 333.090; thus, more provider(s) may qualify.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). The amendment imposes no cost on providers.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3). The amendment broadens laboratory director requirements to those established in KRS 333.090; thus, more provider(s) may qualify.
- (5) Provide an estimate of how much it will cost to implement this administrative regulation:
 - (a) Initially: DMS is unable to accurately predict how many new providers will qualify and enroll as Kentucky Medicaid providers and provide services as a result of the revised laboratory director requirements; therefore, the fiscal impact is indeterminable.
 - (b) On a continuing basis: DMS is unable to accurately predict how many new providers will qualify and enroll as Kentucky Medicaid providers and provide services as a result of the revised laboratory director requirements; therefore, the ongoing fiscal impact is indeterminable.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under the Social Security Act, Title XIX and matching funds of general fund appropriations.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: Neither an increase in fees nor funding is necessary to

implement the amendment to this administrative regulation.

- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: The amendment neither establishes nor increases any fees.
- (9) Tiering: Is tiering applied? (Explain why tiering was or was not used) Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The “equal protection” and “due process” clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

FEDERAL MANDATE ANALYSIS COMPARISON

Regulation Number: 907 KAR 1:028E

Agency Contact: Patricia Biggs or Charles Douglass at (502) 564-2687; Stuart Owen at (502) 564-4321

1. Federal statute or regulation constituting the federal mandate. 42 CFR 441.17, 42 CFR 440.30, 42 USC 1396b(i)(7) and 42 USC 1396a(a)(9).
2. State compliance standards. KRS 205.560 establishes "The scope of medical care for which the Cabinet for Health and Family Services undertakes to pay shall be designated and limited by regulations promulgated by the cabinet, pursuant to the provisions in this section." KRS 333.090 establishes Kentucky laboratory director qualifications.
3. Minimum or uniform standards contained in the federal mandate. State Medicaid programs (via state plan) must cover laboratory services, reimbursement for laboratory services cannot exceed Medicare's reimbursement for laboratory services, and a laboratory or radiological service provider must meet the requirements established in 42 CFR Part 493 to be reimbursed via the Medicaid program.
4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation does not impose stricter than federal requirements.
5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. This administrative regulation does not impose stricter than federal requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Reg NO: 907 KAR 1:028E

Contact Person: Patricia Biggs or Charles Douglass at (502) 564-2687; Stuart Owen at (502) 564-4321

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments or school districts)?

Yes X No

If yes, complete 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services (DMS) will be impacted by the amendment.
3. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. This amendment is authorized by KRS 194A.050(1), 205.520, 205.560, 333.090, 42 CFR 440.30, 441.17, 42 CFR 493, 42 USC 1395l(h)(1)(A), 1396a(a)(9), 1396b(i)(7), and 1396d.
4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
 - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? DMS does not anticipate that the amendment will generate revenue for state or local government.
 - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? DMS does not anticipate that the amendment will generate revenue for state or local government.
 - (c) How much will it cost to administer this program for the first year? DMS is unable to accurately predict how many new providers will qualify and enroll as Kentucky Medicaid providers and provide services as a result of the revised laboratory director requirements; therefore, the fiscal impact is indeterminable.
 - (d) How much will it cost to administer this program for subsequent years? DMS is unable to accurately predict how many new providers will qualify and enroll as Kentucky Medicaid providers and provide services as a result of the

revised laboratory director requirements; therefore, the fiscal impact is indeterminable.

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES

907 KAR 1:028E

Summary of Material Incorporated by Reference

The Department for Medicaid Services is deleting the material incorporated by reference - the "Independent Laboratory and Other Lab and X-ray Services Manual", August 1996 edition. Policies and provisions have been inserted into the administrative regulation itself, rendering the manual unnecessary.